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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
PACKARD, BENJAMIN J	
ART UNIT	**PAPER NUMBER**
4173	

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11/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/772,919	BELANOFF, JOSEPH K.	
	Examiner	Art Unit	
	Benjamin J. Packard	4173	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 15* is/are rejected.

7)☒ Claim(s) 15 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1-11 and 15 are pending, with new claim 15 added on 10/24/2007.

Applicants' arguments, filed 10/24/2007, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Objections

Claim 15 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 15 attempts to limit the glucorticoid receptor antagonist by requiring a specific glucocorticoid receptor antagonist. But the addition of the term "specific" does not limit claim 1, where "a glucocorticoid receptor antagonist" is already recited. Essentially, the use of the term "specific" is synonymous for the term "specific."

Claim Rejections - 35 USC § 102

Claims 1-6, 9-11, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by SCHATZBERG, et al. (US 6,150,349).

1. A method of ameliorating the symptoms of postpartum psychosis in a patient in need thereof,

While the earlier '349 teaches the treatment (inherently ameliorating) of "major depression" (see claim 1), which includes postpartum psychosis where '349 teaches multiple forms of postpartum psychosis ("postpartum psychosis that does not meet other DSM IV categories" column 15 lines 55-56).

comprising administering an amount of a glucocorticoid receptor antagonist effective to ameliorate the symptoms of the postpartum psychosis,

See claim 1.

with the proviso that the first psychotic symptoms arise within nine months of childbirth, that the patient has never suffered any psychotic condition not triggered by childbirth, and that the patient did not suffer from psychosis prior to parturition.

Description of the patient population, where the major depression-type postpartum psychosis includes these parameters.

2. The method of claim 1, wherein the first psychotic symptoms arise within eight weeks of childbirth.

The term postpartum inherently means beginning in or extending into the postpartum period, which includes the first eight weeks after childbirth.

3. The method of claim 1, wherein the glucocorticoid receptor antagonist comprises a steroidal skeleton with at least one phenyl-containing moiety in the 11-β position of the steroidal skeleton.

See claim 2 and column 3 lines 56-61.

4. The method of claim 3, wherein the phenyl-containing moiety in the 11-β position of the steroidal skeleton is a dimethylaminophenyl moiety.

See claim 3 and column 3 lines 56-61.

5. The method of claim 4, wherein the glucocorticoid receptor antagonist comprises mifepristone.

See claim 4 and column 5 lines 13-21.

6. The method of claim 4, wherein the glucocorticoid receptor antagonist is selected from the group consisting of 11β -(4-dimethylaminoethoxyphenyl)-17α-propynyl-17β -hydroxy-4,9 estradien-3-one and 17β-hydroxy-17α-19-(4-methylphenyl)androsta-4,9(11)-dien-3-one.

See column 10, lines 17-20 which teaches RU044, 17β-hydroxy-17α-19-(4-methylphenyl)androsta-4,9(11)-dien-3-one, as another GR antagonist.

9. The method of claim 1, wherein the administration is once per day.

See claim 10.

10. The method of claim 1, wherein the mode of administration is oral.

See claim 11.

11. The method of claim 1, wherein the mode of administration is by a transdermal application, by a nebulized suspension, or by an aerosol spray.

See claim 12.

15. The method of claim 1, wherein the glucocorticoid receptor antagonist is a specific glucocorticoid receptor antagonist.

See claim 1 where "a glucocorticoid receptor antagonist" can be construed to be "a specific glucocorticoid receptor antagonist" as discussed in the claim objection.

Note,

SCHATZBERG et al (US Patent 6.150,349) discloses

> 1. A method of ameliorating psychosis in a patient in need thereof by administration of an amount of a glucocorticoid receptor antagonist effective to ameliorate the psychosis, with the proviso that the patient not be suffering from Cushing's Syndrome and the psychosis is associated with major depression.

(claim 1).

Note, claims 1-11 and 15 are not limited to treating "psychotic major depression" as Applicants suggest, but more broadly, psychosis associated with "major depression." The specification then defines various psychosis states as follows:

> The psychosis ameliorated in the methods of the invention encompasses a broad range of mental conditions and symptoms, as broadly described in the DSM-IV (Kaplan, ed. (1995) supra). Psychosis can refer to a symptom associated with a general medical condition, a disease state or other condition, such as a side effect of drug abuse (a substance-induced disorder) or as a side effect of a medication. While the practitioner can use any set of proscribed or empirical criteria to diagnose the presence of a psychosis as an indication to practice the methods of the invention, some illustrative diagnostic guidelines and examples of relevant symptoms and conditions are described below.

(Column 12 lines 34-42). It should be noted that among the broad range of mental conditions and symptoms that a practitioner can detect, as broadly described in the DSM-IV, are conditions or illnesses involving psychosis which can be classified as a

psychotic disorder not otherwise specified, including "postpartum psychosis that does not meet other DSM categories" (column 15 lines 54-56). These mental conditions and symptoms are disclosed to be treated by the methods of the invention.

Therefore, SCHATZBERG et al does disclose the method of ameliorating psychosis in postpartum depression. Because there is no definition for "major depression" as claimed in claim 1, postpartum depression is being interpreted to be a major depression as recognized as a condition involving psychosis and recognized, but not categorized by the DSM-IV classifications.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over SCHATZBERG, et al. (US 6,150,349) in view of BRADLEY et al, J. Med. Chem. 45, 2417-2424 (2002).

SCHATZBERG, et al does not teach when the specific glucocorticoid receptor antagonists listed in claim 7.

BRADLEY et al, J. Med. Chem. 45, 2417-2424 (2002) teach GR antagonist compounds (see title, abstract, and pg 2417 first full paragraph) 4α(S)-Benzyl-2(R)-prop-l-ynyl- 1,2,3,4,4α,9,10,10α(R)-octahydro-phenanthrene-2,7-diol diol (pg 2421 3rd full paragraph)and 4α(S)-Benzyl-2(R)- chloroethynyl-1,2,3,4,4α,9,10,10α(R)-octahydro-phenanthrene-2,7-diol (pg 2421 2nd full paragraph). Therefore, one skilled in the art would recognize the ability to substitute compounds that have the same glucocorticoid receptor antagonistic properties, and would have a reasonable expectation of success.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over SCHATZBERG, et al. (US 6,150,349) as applied to claim 1 above, and further in view of GEBHARD (US 6,011,025).

SCHATZBERG, et al does not teach when the specific glucocorticoid receptor antagonists listed in claim 8.

GEBHARD claims the glucocorticoid receptor antagonist (11β,17β)- 11-(1,3-benzodioxol-5-yl)-17-hydroxy-17-(1 -propynyl)estra-4,9-dien-3-one (see abstract and claim 6).Therefore, one skilled in the art would recognize the ability to substitute compounds that have the same glucocorticoid receptor antagonistic properties, , and would have a reasonable expectation of success.

Applicants argue the 103 rejection should be withdrawn as a result of SCHATZBERG et al. not disclosing the treatment of postpartum depression. As explained above, Examiner finds SCHATZBERG et al does disclose the treatment of postpartum psychosis with a glucocorticoid receptor antagonist. Therefore, the rejection is maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-11 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 and 10-12 of SCHATZBERG, et al. (US 6,150,349) (hereafter '349). Although the conflicting claims are not identical, they are not patentably distinct from each other because they both are directed to methods of treating depression. See the above 102 and 103 arguments above for support of the anticipation and obviousness.

While possibly an academic rejection, the double patenting rejection is still a valid rejection. As such, the rejection is maintained.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Examiner cites, Chrousos et al, Annals of Internal Medicine, Vol 129, no. 3 (1998), which teaches Corticotropin-releasing hormone (CRH) and CRH induced proopiomelanocortin peptides inhibit hypothalamic gonadotropin-releasing hormone secretion, whereas glucocorticoids suppress pituitary luteinizing hormone and ovarian estrogen and progesterone secretion and render target tissues resistant to estradiol. The hypercortisolism of the latter half of pregnancy can be explained by high levels of placental CRH in plasma. This hypercortisolism causes a transient postpartum adrenal suppression that, together with estrogen withdrawal, may partly explain the depression and autoimmune phenomena of the postpartum period. (See abstract)

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin J. Packard whose telephone number is 571-270-3440. The examiner can normally be reached on M-R 9-4:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

5 November 2007
BP

Ardin H. Marschel 11/9/07
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SUPERVISORY PATENT EXAMINER